



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF RESEARCH AND DEVELOPMENT
HEALTH EFFECTS RESEARCH LABORATORY

CINCINNATI, OHIO 45268

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Eunice E. Sigurdson, R.N., M.P.H.
Chronic Disease Epidemiologist
Minnesota Department of Health
717 S.E. Delaware Street
Minneapolis, Minnesota 55440

US EPA RECORDS CENTER REGION 5



515290

Dear Ms. Sigurdson:

I have reviewed your proposal to further investigate the apparently elevated rates of breast cancer in St. Louis Park to determine if an increased risk is related to exposure to polycyclic organic compounds. Although I agree that additional work is warranted to examine this problem, more detailed planning is needed to clarify and expand the described approach prior to initiating the study.

There are a number of questions regarding exposure of the population to the toxic compounds that are not clear from your description. ① What is the geographic relationship of St. Louis Park to the other suburbs mentioned and how is this related to water supplies? ② Why is it assumed that St. Louis park alone has been impacted by the chemicals? ③ How many wells serve this area and how many have been tested for polycyclics? ④ What amount of the population was served by the 4 wells closed in 1978? ⑤ Have the areas neighboring St. Louis Park, particularly those in the path of water table flow, been monitored for the organic chemical pollutants? It would obviously be important to document that no exposure exists where comparison cases are to be chosen. ⑥ Are there suspected or measured gradients of exposure within St. Louis Park that could be examined in relation to breast cancer rates? This is indicated in the census tract map but it is not very clearly related to exposure or to rates in presumably unexposed neighboring communities. ⑦ Are there considered to be any other likely routes of exposure besides drinking water? In general, the exposure aspects of this investigation need further documentation to explain how St. Louis Park is considered to be the impacted community and what the boundaries and gradients of exposure might be.

In regards to the proposed study methods, it does not appear to be case-control design. Cases from exposed and unexposed cohorts are being compared. The objective is to determine if the underlying populations are similar with respect to known risk factors by comparing the distribution of these risk factors in the different case groups. I am not certain of the epidemiologic soundness of this approach.

Rate $\bar{S} RF = \left(\frac{a + SRR}{N} \right) \text{Rate}$

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Medical Records

Prior to initiating contact with cases or next of kin would it be possible to obtain some of the risk factor data from medical records, it still seems as though this might be a worthwhile step prior to contacting cases. One point in favor of such an approach would be the fact that next of kin may not be better sources for obtaining much of the risk factor data. Of course this would depend on the difficulty of obtaining access to medical records *Burton*

If contacting exposed and unexposed cases is necessary then additional description of the methods to be used to contact these subjects, and of the manner in which the study is to be presented to them, is needed. Will permission be obtained from the patients' physicians for the interview or medical records?

One area neglected in this proposal is the statistical aspects of the study. I am concerned that even if 70-80 exposed cases can be located and interviewed, because there are multiple risk factors (probably 4-5 major ones), and because the relative risks associated with these factors may not be well quantified, that it may be very difficult to determine if varying distributions of these factors in exposed and unexposed cases account for the different incidence rates. What statistical techniques are to be used to compare risk factor distributions and how do sample size limitations affect your ability to answer questions about the relative contributions of the measured parameters?

In addition to the risk factors stated in the proposal there are several additional ones that possibly should be added. These are medication use, particularly estrogens and progesterone, benign breast disease, and relevant medical history such as previous cancer history. I doubt that a dietary history would be of much use.

Thank you for the proposal and I look forward to your comments on these points.

Sincerely yours,

Robert K. Miday

Robert K. Miday, M.D.

Medical Officer

Chronic Diseases & Biostatistics Program
Field Studies Division

Care-Control Residence

Most trends

SM.S.A. 40-50,000

from

SLP. - wells

Richfield - wells

Edna -

Mpls - MISSISSIPPI

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*Based on
addition of
of old 20 ✓ (1/2)
1st old 325 ✓ 2/3
Jewell 15 ✓ 3/3
* Active
* Alt. 2/10 ✓ (1/5)*

[a + b] / N